Substitute for form 1449A/PTO

Sheet

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

1	of	4

Complete if Known			
Application Number Divisional of 10/014,750			
Filing Date	Filed Herewith		
First Named Inventor	Jenny LOUIE-HELM et al.		
Art Unit	Unassigned		
Examiner Name	Unassigned ·		
Attorney Docket Number	3100-0003.10		

U.S. PATENT DOCUMENTS							
Examiner Initials*	Cite No.	Document No.	Issue Date or Publication Date	Name of Patentee or Applicant of Cited Document	Class	Subclass	Filing Date if Appropriate
_b/=	AA	3,960,150	6/1/76	Hussain et al.			
	AB	4,434,153	2/28/84	Urquhart et al.	<u> </u>		
	AC	4,690,824	9/1/87	Powell et al.	1	<u> </u>	/
	AD	4,695,467	9/22/87	Uemura et al.	<u> </u>		
	AE	4,748,023	5/31/88	Tamás et al.			
	AF	4,786,503	11/22/88	Edgren et al.	<u> </u>		
	AG	4,839,177	6/13/89	Colombo et al.			
	AH	4,851,232	. 7/25/89	Urquhart et al.	 		
	Al	4,865,849	9/12/89	Conte et al.	<u> </u>		
	AJ	5,002,772	3/26/91	Curatolo et al.			
	AK	5,007,790	4/16/91	Shell			
	AL	5,064,656	11/12/91	Gergely et al.			
	AM	5,085,865	2/4/92	Nayak			
	AN	5,213,808	5/25/93	Bar-Shalom et al.			
	AO	5,232,704	8/3/93	Franz et al.			
	AP	5,393,765	2/28/95	Infeld et al.			
	AQ	5,422,123	6/6/95	Conte et al.			I/
	AR	5,425,950	6/20/95	Dandiker et al.			/
	AS	5,487,901	1/30/96	Conte et al.			
	AT	5,508,040	4/16/96	Chen			
	AU	5,549,913	8/27/96	Colombo et al.			
	AV	5,582,837	10/10/96	Shell	<u> </u>		
	AW	5,609,590	3/11/97	Herbig et al.			
	AX	5,626,874	5/6/97	Conte et al.			
	AY	5,635,210	6/3/97	Allen, Jr. et al.			
	AZ	5,650,169	7/22/97	Conte et al.			
	BA	5,651,985	7/29/97	Penners et al.			
	BB	5,681,583	10/28/97	Conte et al.			
	BC	5,688,776	11/18/97	Bauer et al.			
	BD	5,736,159	4/7/98	Chen et al.		/	
	BE	5,738,874	4/14/98	Conte et al.		V	
	BF	5,780,057	7/14/98	Conte et al.			
	BG	5,783,212	7/21/98	Fassihi et al.			
	ВН	5,811,126	9/22/98	Krishnamurthy			
	BI	5,827,984	10/27/98	Sinnreich et al.			
	BJ	5,837,379	11/17/98	Chen et al.	LT		
	BK	5,840,329	11/24/98	Bai .			
	BL	5,840,332	11/24/98	Lerner et al.	$\perp I$		
	ВМ	5,861,173	1/19/99	Nishioka et al.	IT		
	BN	5,891,474	4/6/99	Busetti et al.	\coprod		
	ВО	5,897,874	4/27/99	Stevens et al.	II		
	BP	5,916,595	6/29/99	Chen et al.			
ME	BQ	5,945,125	8/31/99	Kim			
OT							

Examiner	21 - 1		Date	0.00
Signature	Blessing	tubara	Considered	2-24-03

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Substitute for form 1449A/PTO

Sheet

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

2	of	4

Complete if Known				
Application Number	Divisional of 10/014,750			
Filing Date	Filed Herewith			
First Named Inventor	Jenny LOUIE-HELM et al.			
Art Unit	Unassigned			
Examiner Name	Unassigned			
Attorney Docket Number	3100-0003.10			

			U.S. PATENT I	DOCUMENTS			
Examiner Initials*	Cite No.	Document No.	Issue Date or Publication Date	Name of Patentee or Applicant of Cited Document	Class	Subclass	Filing Date if Appropriate
55-	BR	5,972,389	10/26/99	Shell et al.			
i	BS	6,027,748	2/22/00	Conte et al.			
	BT	6,033,685	3/7/00	Qiu et al.			
	BU	6,066,337	5/23/00	Allen et al.			
	BV	6,093,420	7/25/00	Baichwal			
	BW	6,120,803	9/19/00	Wong et al.			
	вх	6,174,497	1/16/01	Roinestad et al.			
	BY	6,177,104	1/23/01	Allen et al.			
	BZ	6,187,337	2/13/01	Allen et al.			
	CA	6,207,197	3/27/01	Illum et al.		7	
	CB	6,221,395	4/24/01	Maggi et al.		/	
	CC	6,261,601	7/17/01	Talwar et al.			
	CD	6,340,475	01/22/02	Shell et al.	7		
	CE	6,368,628	4/9/02	Seth			
	CF	6,451,808	9/17/02	Cowles			
	CG	6,488,962	12/3/02	Berner et al.	1/		
126	СН	2001/0018070	8/30/01	Shell et al.	/		
	-	Serial No. 09/425,491	10/22/99	Shell et al			10/22/99
	급	Serial No. 10/029,134	10/25/01	Gusler et al.			10/25/01_
	_CK-	Serial No. 10/045,823	11/6/01	Shell et al.			11/6/01
	_CL	Serial No. 10/066,146	2/1/02	Lim et al.			2/1/02
	CM	Serial No. 10/152,914	5/20/02	Fara et al.			5/20/02
	CN	Serial No. 10/280,309	10/25/02	Berner-et-al.			10/25/02_
_	CO_	Serial No. 10/280,852	10/25/02	Devane et al.			10/25/02-

		FOREIG	N PATENT DOCUME	NTS				
Examiner Initials*	Cite No.	Foreign Patent Document No. Publication Date Country		Foreign Patent Document No. Publication Date Country		Class	Subclass	Т
150	CP	EP 0598309 B1	1/28/98	Europe				
	CQ	EP 0795324 A2	9/17/97	Europe				
	CR	GB 1330829	9/19/73	United Kingdom			Γ	
	CS	WO 96/32097 A1	10/17/96	PET WO			Γ	
	СТ	WO 98/55107 A1	12/10/98	PCT (JU)		7	Г	
	CU	WO 00/23045 A1	4/27/00	PCT LUL		/	Г	
7	CV	WO 00/38650 A1	7/6/00	PCT WU			T	
	CW	WO 01/32217 A3	5/10/01	PCT WV			Γ	
	CX	WO 01/56544 A3	8/9/01	PCT / LI	7		Г	
	CY	WO 01/97783 A1	12/27/01	PCT M()	7		Γ	
Dor	CZ	WO 02/083687 A1	10/24/02	PCT (J)	/		T	

Examiner Ble Sing Fubara Date Considered 2-24-05

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

* Pending application, Not prior Act

*)

Complete if Known Substitute for form 1449A/PTO Divisional of 10/014,750 **Application Number** Filing Date Filed Herewith INFORMATION DISCLOSURE Jenny LOUIE-HELM et al. **First Named Inventor** STATEMENT BY APPLICANT **Art Unit** Unassigned (use as many sheets as necessary) Unassigned **Examiner Name** of 4 Attorney Docket Number 3100-0003.10 Sheet

			OTHER DOCUMENTS — NONPATENT LITERATURE DOCUMENTS	
Exam		Cite	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), Title of the item (book, magazine,	Т
Initia	als*	No.	journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	
P	5F1	DA	ABRAHAMSSON et al. (1993), "Absorption, Gastrointestinal Transit, and Tablet Erosion of Felodipine	l
i			Extended-Release (ER) Tablets," Pharmaceutical Research 10(5):709-714.	<u> </u>
		DB	APICELLA et al. (1993), "Poly(ethylene oxide) (PEO) and Different Molecular Weight PEO Blends	l
			Monolithic Devices for Drug Release," Biomaterials 14(2):83-90.	<u> </u>
		DC	BAUMGARTNER et al. (2000), "Optimisation of Floating Matrix Tablets and Evaluation of Their Gastric	ļ
			Residence Time," International Journal of Pharmaceutics 195:125-135.	<u>L_</u>
		DD	BETTINI et al. (1994), "Swelling and Drug Release in Hydrogel Matrices: Polymer Viscosity and Matrix	
			Porosity Effects," European Journal of Pharmaceutical Sciences 2:213-219.	
-1		DE	CHEN et al. (2000), "Gastric Retention Properties of Superporous Hydrogel Composites," Journal of	
- 1			Controlled Release 64:39-51.	
		DF	COLUMBO et al. (1990), "Drug Release Modulation by Physical Restrictions of Matrix Swelling,"	Г
			International Journal of Pharmaceutics 63:43-48.	
		DG	DAVIS et al. (1986), "The Effect of Density on the Gastric Emptying of Single- and Multiple-Unit Dosage	
	1		Forms," Pharmaceutical Research 3(4):208-213.	1
_	\neg	DH	DESHPANDE et al. (1997), "Development of a Novel Controlled-Release System for Gastric Retention,"	Т
			Pharmaceutical Research 14(6):815-819.	l
-		DI	FORD et al. (1987), "Importance of Drug Type, Tablet Shape and Added Diluents on Drug Release	1
			Kinetics from Hydroxypropylmethylcellulose Matrix Tablets," International Journal of Pharmaceutics	
			40:223-234.	
-		DJ	GAO et al. (1996), "Swelling of Hydroxypropyl Methylcellulose Matrix Tablets. 2. Mechanistic Study of	t^-
			the Influence of Formulation Variables on Matrix Performance and Drug Release," Journal of	1
			Pharmaceutical Sciences 85(7):732-740.	l
-	_	DK	HWANG et al. (1998), "Gastric Retentive Drug-Delivery Systems," Critical Reviews in Therapeutic Drug	†
l		DK	Carrier Systems 15(3):243-284.	i
-		DL	JU et al. (1995), "Drug Release from Hydrophillic Matrices. 1. New Scaling Laws for Predicting Polymer	
		DL	and Drug Release Based on the Polymer Disentanglement Concentration and the Diffusion Layer,"	1
			Journal of Pharmaceutical Sciences 84(12):1455-1463.	l
\vdash		DM	JU et al. (1995), "Drug Release from Hydrophillic Matrices. 2. A Mathematical Model Based on the	
		DIVI	Polymer Disentanglement Concentration and the Diffusion Layer," Journal of Pharmaceutical Sciences	l
			84(12):1464-1477.	i
-+		DN	KANIWA et al. (1983), "The Bioavailability of Flufenamic Acid and Its Dissolution Rate from Capsules,"	✝
		אט	International Journal of Clinical Pharmacology, Therapy and Toxicology 21(2):56-63.	1
		DO		╁
		DO	KATORI et al. (1995), "Estimation of Agitation Intensity in the GI Tract in Humans and Dogs Based on in	
├			Vitro/in Vivo Correlation," Pharmaceutical Research 12(2):237-243.	
		DP	KIM (1995), "Drug Release from Compressed Hydrophilic POLYOX-WSR Tablets," Journal of	1
$\vdash \dashv$			Pharmaceutical Sciences 84(3):303-306.	—
	Į.	DQ	LAPIDUS et al. (1966), "Some Factors Affecting the Release of a Water-Soluble Drug from a Compressed	1
\vdash			Hydrophilic Matrix," Journal of Pharmaceutical Sciences 55(8):840-843.	├
		DR	LAPIDUS et al. (1968), "Drug Release from Compressed Hydrophilic Matrices," Journal of	1
			Pharmaceutical Sciences <u>57(8)</u> 1292-1301.	<u> </u>
		DS	MAGGI et al. (2000), "High Molecular Weight Polyethylene Oxides (PEOs) as an Alternative to HPMC in	1
			Controlled Release Dosage Forms," International Journal of Pharmaceutics 195:229-238.	
1 D	6	DT	MAGGI et al. (2000), "Highly Swellable Multi-Layer Tablets to Prolong the Residence Time of the	
ıυ			Delivery in the Stomach," Journal of Controlled Release 64:269-347.	l

$1 \sim 1.70 \times 10^{-1}$	Date Considered	2-24-05
------------------------------	--------------------	---------

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Complete if Known Substitute for form 1449A/PTO Divisional of 10/014,750 **Application Number** Filed Herewith Filing Date INFORMATION DISCLOSURE Jenny LOUIE-HELM et al. First Named Inventor STATEMENT BY APPLICANT Unassigned Art Unit (use as many sheets as necessary) **Examiner Name** Unassigned 3100-0003.10 4 **Attorney Docket Number** Sheet of

		OTHER DOCUMENTS — NONPATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), Title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Т
W.	DU	OTH et al. (1992), "The Bilayer Floating Capsule: A Stomach-Directed Drug Delivery System for Misoprostol," Pharmaceutical Research 9(3):298-302.	
1	DV	RAO et al. (1988), "Swelling Controlled-Release Systems: Recent Developments and Applications," International Journal of Pharmaceutics 48:1-13.	
	DW	REYNOLDS et al. (1998), "Polymer Erosion and Drug Release Characterization of Hydroxypropyl Methylcellulose Matrices" <i>Journal of Pharmaceutical Sciences</i> 87(9):1115-1123.	
	DX	SHAMEEM et al. (1995), "Oral Solid Controlled Release Dosage Forms: Role of GI-Mechanical Destructive Forces and Colonic Release in Drug Absorption Under Fasted and Fed Conditions in Humans," <i>Pharmaceutical Research</i> 12(7):1049-1054.	
(DY	SIEPMANN et al. (1999) "HPMC Matrices for Controlled Drug Delivery: A New Model Combining Diffusion, Swelling, and Dissolution Mechanisms and Predicting the Release Kinetics" <i>Pharmaceutical Research</i> 16(11):1748-1756.	
BF	DZ	YANG et al. (1996), "Zero-Order Release Kinetics from a Self-Correcting Floatable Asymmetric Configuration Drug Delivery System," <i>Journal of Pharmaceutical Sciences</i> 85(2):170-173.	

			and the second s	
Examiner	Di col	Fuhara	Date	2-2
Signature	Blesong	1 115219	Considered	2 24 05